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EH 52R (12/06)

## BIENNIAL DRUG MANUFACTURING LICENSE RENEWAL APPLICATION PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED See Page 2 for Instructions.

Individual/Sole Proprietorship   Partnership   Corporation/Limited Liability Company   Nonprofit   Other:	<ul> <li>NO CHANGES FROM PREVIOUS APPLICATION ☐ APPLICATION</li> <li>Name of Firm</li> </ul>						Facility Operator (name and title)					
3. Facility Address (currierund) 4. Facility Address (currierund) 5. City 5. City 6. Naling Address (currierund) 6. Naling Address (currierund) 7. Mailing Add	O. DDA (List additional DDA)						E. W. E. L. N. J.		144	E W EAVA		
4. Folity Address (continued) 5. City 5. State 7. Mailing Address (of different or P.O. Box number) 7. Mailing Address (of different or P.O. Box number) 7. Mailing Address (ordinued) 8. City 8. City 8. State 7. Mailing Address (continued) 9. Compression of the transcription of the	2. UBA (List additional UBAs on separate sheet if necessary.)					10.	( )		11.	( )	umber	
5. City State   ZIP Code   15. Correspondent Telephone Number   16. Correspondent FAX Number   17. Country (if other than United States)   18. FDA CFN or FEI Number   17. Country (if other than United States)   18. FDA CFN or FEI Number   19. Web atte (LRC)   1							( )		13.	E-Mail Address	3	
Mailing Address (if different or P.O. Box number)	Facility Address (continued)						Correspondent (name and	title)				
7. Mailing Assress (continued)  8. City  8. City  9. State  2. Code  9. Interstate Commerce  1. Type of Ownership  9. Product Shipped  1. Type of Ownership  9. Product Shipped  1. Type of Ownership  9. Partnership  1. Corporation/Limited Liability Company  1. Nonprofit  1. State of Incorporation  2. Owners' or Officers' Names and Titles  2. Stage of Manufacturing products  1. Validation - Completion Date:  1. Validation - Completion Date:  2. Owners' or Officers' Names and Titles  2. Stage of Manufacture at Date of Application (check all that apply)  1. Validation - Completion Date:  2. Owners' or Officers' Names and Titles  2. Stage of Manufacturing products  2. Owners' or Officers' Names and Titles  2. Stage of Manufacturing products  2. Type of Drug Product Check all that apply)  1. Prescription or Booth is checked refer to PDMA requirements on instruction page 2.  2. Drug Products Manufactured at this Location (check all that apply)  1. Owners' of Drug Product Check all that apply)  1. Owners' of Drug Product Check all that apply)  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  2. Drug Products Manufactured at this Location (check all that apply)  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Check all that apply  1. Owners' of Drug Product Chec	5.	City		State	ZIP Code	15.	Correspondent Telephone N	lumber	16.	Correspondent (	FAX Number	
8. City   State   ZIP Code   20. Interestate Commerce   Product Shipped   Product or Raw Materials Received   N/A   27. Type of Ormership   Partnership   Corporation/Limited Liability Company   Nonprofit   Other:   28. Size of Facility (square feet):   Number of Employees at this Facility:   29. Stage of Manufacturing products   Plant construction/design (Targeted Completion Date:   Other (specify):   29. Interestate distribution   Human cinical trials (investigational use)   California distribution only   U.S. distribution   Export market   20. Type of Dury Pooduct (leck all that usply)   Plant construction/design (Targeted Completion Date:   Other (specify):   20. Type of Dury Pooduct (leck all that usply)   California distribution only   U.S. distribution   Export market   21. Type of Dury Pooduct (leck all that usply)   Plant construction/design (Targeted Completion Date:   Dury Pooduct (leck all that usply)   Plant construction/design (Targeted Completion Date:   Dury Pooduct (leck all that usply)   Plant construction/design (Targeted Completion Date:   Dury Pooduct (leck all that usply)   Plant construction/design (Targeted Completion Date:   Dury Pooduct (leck all that usply)   Plant construction/design (Targeted Completion Date:   Dury Pooduct (leck all that usply)   Plant construction or Substitution only   U.S. distribution   Export market   Dury Pooduct (leck all that usply)   Plant construction or Substitution only   U.S. distribution   Export market   Dury Prescription or Both is checked refer to PDMA requirements on instruction page 2.   Dury Pooduct (leck all that usply)   Plant construction or Substitution or Pooduct (leck all that usply)   Plant construction or Pooduct (leck all that usply)   Plant construction or Pooduct (leck all that usply)   Plant construction or Pooduct (leck all that usply)   Plant (leck all tha	Mailing Address (if different or P.O. Box number)						Country (if other than United	States)	18.	FDA CFN or FE	El Number	
Product Shipped   Product or Raw Materials Received   N/A	7. Mailing Address (continued)						Web site (URL)					
Gorporate Name (If applicable)   State of Incorporation/Limited Liability Company   Nonprofit   Other:	8.	City		State	ZIP Code	20.		☐ Product or Ra	w Ma	aterials Receiv	ved □ N/A	
State of Incorporation   State of Incorporation			shin 🗆	Partnershin	☐ Corporation	n/l in	nited Liability Company	□ Nonprofit	ПС	)ther		
24. Size of Facility (square feet):    Number of Employees at this Facility:		_	stilb 🗀	aitheiship	<u> </u>			Пиоприя		/tilei		
24. Size of Facility (square feet):    Number of Employees at this Facility:	00											
Stage of Manufacturic at Date of Application (check all that apply)   Plant construction/design (Targeted Completion Date:   Different construction Date:   Different Date:	23. 	23. Owners' or Officers' Names and Titles					Owners' or Officers' Names and Titles					
Stage of Manufacturic at Date of Application (check all that apply)   Plant construction/design (Targeted Completion Date:   Different construction Date:   Different Date:												
Manufacturing products   Plant construction/design (Targeted Completion Date:   Other (specify):						Nur	mber of Employees at this	s Facility:				
Validation - Completion Date:			Application (c	heck all that		Dia	ot construction/decian /Te	argeted Completion	. Dot	•	`	
Intended Drug Destination (check all that apply)		_	loto:					argeted Completion	n Dati	e:	)	
Commercial distribution   Human clinical trials (investigational use)   California distribution only   U.S. distribution   Export market	26			·/\	Ц	Oth	er (specify)					
Type of Drug Product (check all that apply)	20.	- · · · · · · · · · · · · · · · · · · ·			als (investigational	use	)	ition only □ U.	S. dis	stribution [	Export market	
Drug Products Manufactured at this Location (check all that apply)	27.	Type of Drug Product (check all the	hat apply)		( <del>-</del> <del>-</del> <del>-</del>						<u> </u>	
700 Bulk pharmaceuticals (API)   704 Controlled substances   707 Biotech   711 Pre-IND   710 Medical gases   (Schedule: DEA #: ) 708 Biologics   712 Topical   712 Topical   703 Veterinary   703 Veterinary   706 Investigational New Drug   709 Parenteral   709 Parenteral   709 Parenteral   709 Parenteral   705 Approved New Drug   709 Parenteral						ript	ion or Both is checked	refer to PDMA red	uire	ments on ins	truction page 2.	
701 Medical gases   (Schedule: DEA #: )   708 Biologics   712 Topical   702 Radioactive   705 Approved New Drug   709 Parenteral   Other (specify):   708 Investigational New Drugs (IND)   710 Oral Dose (solid/liquid)   29. Manufacturing processes/activities employed or planned in the manufacture of the drugs listed above. Indicate if these processes/activities will be done at thi location (in-house) or by a contract. List other processes using additional sheets, if necessary. (Check at least one or more.)    Processes/Activities   In-house   Contract   In-house   Contract   Processes/Activities   In-house   Contract   Processes/Activities   In-house   Contract   Processes/Activities   In-house   In-house   In-house   Contract   In-house   In-	28.	Drug Products Manufactured at th ☐ 700 Bulk pharmaceuticals	his Location ( (API)	check all that 704 Control	t apply) led substances		□ 707	Biotech		☐ 711 Pr	e-IND	
703 Veterinary		_		,		\ #: <sub>-</sub>					•	
29. Manufacturing processes/activities employed or planned in the manufacture of the drugs listed above. Indicate if these processes/activities will be done at thi location (in-house) or by a contract. List other processes using additional sheets, if necessary. (Check at least one or more.)    Processes/Activities						(INII	<del></del> -		auid)		(specify):	
Processes/Activities In-house Contract  Aerosolization  Aseptic  Coating  Relabel Only  Emulsification  Encapsulation  Encapsulation  Fermentation/tissue culture viral vector/gene therapy Liquid Mixing  30. Payment Codes (Check only one code—see page 2 for schedule)  AKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES See page 2 for mailing address  The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by CA Health and Safety Code, §111630.  By signature, I declare under penalty of perjury that all information provided herein is true and correct.  PLEASE DO NOT WRITE BELOW THIS LINE.  License Number  Expiration Date  Payment Type  Amount	29.	Manufacturing processes/act	ivities empl	oyed or pla	nned in the manuf	actu	re of the drugs listed abo	ve. Indicate if the	se pi	rocesses/activ	rities will be done at this	
Aerosolization   Powder Mixing     Powder Mixing     Powder Mixing   Powder Mi					_	al sl	-		more.			
Aseptic Coating Coatin			es in-i	nouse □	Contract			cesses/Activities		in-nous		
Fermentation/tissue culture viral vector/gene therapy Liquid Mixing Other (Specify):		Aseptic									· · · · · · · · · · · · · · · · · · ·	
Fermentation/tissue culture viral vector/gene therapy Liquid Mixing Other (Specify):		3										
Fermentation/tissue culture viral vector/gene therapy Liquid Mixing Other (Specify):												
Vector/gene therapy Liquid Mixing    30. Payment Codes (Check only one code—see page 2 for schedule)   31. License Fees Due:   A—\$2600   B—\$1700   \$   \$   \$   \$   \$   \$   \$   \$   \$		•	iral	H	H		•				님	
Liquid Mixing			IIai	Ш							H	
a. License Fee (see #30)  MAKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES See page 2 for mailing address  The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by CA Health and Safety Code, §111630.  By signature, I declare under penalty of perjury that all information provided herein is true and correct.  32. Signature  Printed Name  Title  Date  PLEASE DO NOT WRITE BELOW THIS LINE.  License Number  Expiration Date  Date Received  Payment Type  Amount							(op)					
MAKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES See page 2 for mailing address  C. Late Fee (\$10 if over 30 days late) d. Total Payment Due  The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by CA Health and Safety Code, §111630.  By signature, I declare under penalty of perjury that all information provided herein is true and correct.  32. Signature  Printed Name  Title  Date  PLEASE DO NOT WRITE BELOW THIS LINE.  License Number  Expiration Date  Date Received  Date Received  Amount	30.			-see page 2	? for schedule)			#20)			er Each Fee Below:	
See page 2 for mailing address  C. Late Fee (\$10 if over 30 days late) d. Total Payment Due  S  The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by CA Health and Safety Code, §111630.  By signature, I declare under penalty of perjury that all information provided herein is true and correct.  32. Signature  Printed Name  Title  Date  PLEASE DO NOT WRITE BELOW THIS LINE.  License Number  Expiration Date  Date Received  Payment Type  Amount		A\$2000B	-φ1700				,	,	200			
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By signature, I declare under penalty of perjury that all information provided herein is true and correct.  32. Signature Printed Name Title Date  PLEASE DO NOT WRITE BELOW THIS LINE.  License Number Expiration Date Date Received Payment Type Amount		See page	2 for mail	ing addres	S		·					
32. Signature Printed Name Title Date  PLEASE DO NOT WRITE BELOW THIS LINE.  License Number Expiration Date Date Received Payment Type Amount	The	Food and Drug Branch MU	IST BE NO	TIFIED of a	ny change in the	appl	-		ealth	and Safety C	Code, §111630.	
PLEASE DO NOT WRITE BELOW THIS LINE.  License Number Expiration Date Date Received Payment Type Amount		· · · · · · · · · · · · · · · · · · ·			•	ovio		orrect.			Doto	
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License Number Expiration Date Date Received Payment Type Amount					PLEASE DO N	OT I	NRITE BELOW THIS LII	VE.				
	Lice	ense Number E	Expiration Da	te								

## BIENNIAL DRUG MANUFACTURING LICENSE RENEWALAPPLICATION INSTRUCTIONS

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application and make check payable to: <u>DEPARTMENT OF HEALTH SERVICES</u>. The fee must accompany this application or it cannot be processed. **Please apply within 30 days of expiration**; failing to do so requires an additional \$10 penalty added to the renewal fee before the license is issued. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

Renewal Status: Place an (X) in the box next to "No Changes from Previous Application" if your firm does not have any changes to report since you last applied for or renewed a Drug Manufacturing License at this location under the current ownership. Place an (X) in the box next to "Application Reflects Changes...", if your firm has new information to report other than a location or ownership change, and you are renewing that license. This license is non-transferable. If your firm has changed location, ownership, or both, use the application titled "New Drug Manufacturing License Application" (EH 52N). For any section that does not apply to your company, please indicate with (N/A). Do not leave any sections blank.

- 1. Name of Firm: Enter full name of business, corporation, company, or organization applying for licensure.
- 2. **DBA:** Enter any other name(s) your company is doing business as.
- 3.-5. Facility Address: Enter the number, street, city, state, and ZIP code for this facility location.
- 6.-8. Mailing Address: Enter the full mailing address if different from the facility address.
  - 9. Facility Operator: Enter the full name(s) of the person(s) in charge of drug manufacturing at this facility and their title(s).
  - 10. Facility Telephone Number: Enter daytime business telephone number of this facility.
  - 11. Facility FAX Number: Enter facility FAX number.
  - 12. 24 Hour Emergency Telephone Number: Enter telephone number to be called in the event of an emergency.
  - 13. E-mail Address: Enter facility e-mail address.
  - 14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
  - 15. Correspondent Telephone Number: Enter the daytime business telephone number of the contact person.
  - 16. Correspondent FAX Number: Enter the daytime business FAX number of the contact person.
  - 17. Country: Enter the country where your facility is located, if outside of the United States.
  - 18. FDA CFN or FEI: Enter your US Food and Drug Administration Central File Number or Federal Establishment ID, if known.
  - 19. **Web site:** Enter the Web site address for your business, if applicable.
  - 20. **Interstate Commerce:** Place an (X) in all appropriate boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
  - 21. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
  - 22. Corporate Name: Enter corporate name if applicable. Enter state of incorporation if applicable.
  - 23. Owners' or Officers' Names: List the business owners' or officers' names and titles. USE ADDITIONAL SHEETS IF NECESSARY.
  - 24. Size of Facility: Indicate the most appropriate size (in square feet) at this facility and the approximate number of employees at the facility.
  - 25. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
  - 26. Intended Drug Destination: Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
  - 27. **Types of Products:** Place an (X) in each box that applies to the type of drugs manufactured or to be manufactured. For human prescription (Rx) drug manufacturers, refer to PDMA requirements below\*.
  - 28. **Products Manufactured:** Place an (X) in the box adjacent to each product area box that applies to the drugs manufactured or to be manufactured. Use additional sheets if necessary.
  - 29. **Manufacturing Processes:** Place an (X) in the columns adjacent to all applicable processes to be performed in-house and/or contracted-out. Leave line blank if the indicated process will not be applied to the manufacturing of listed drugs. List additional processes or methods as needed herein or on additional sheets if necessary.
  - 30. **Payment Fee Code:** Your renewal license fee is based on the application type, number of employees, amount of sales, and the type of drugs being manufactured at the facility.

Application Type	Biennial Fee	Late Fee	Payment Interval	Payment Code
Renewal	\$2600	\$10	Biennially on Renewal	A
Renewal (**Special/Small Firms)	\$1700	\$10	Biennially on Renewal	В

<sup>\*\*</sup> Special or Small Firms are types limited to companies that 1) repack medical gas only, OR 2) employ three or fewer people and have an annual sales of less than \$500,000.

- \* PDMA (Prescription Drug Marketing Act) Requirements: If your firm manufactures human prescription (Rx) drugs, an additional \$200.00 must be added to the license renewal fee and a Disclosure Statement (Form EH 53) must be submitted for each person listed on lines #9 and #23 (instructions provided therein). Information relevant to the PDMA, (e.g., Disclosure Statements and Applicant Fingerprint Live Scan requirements) can be reviewed at: <a href="http://www.dhs.ca.gov/fdb/HTML/Drug/PDMA.htm">http://www.dhs.ca.gov/fdb/HTML/Drug/PDMA.htm</a>.
- 31. License Renewal Fee Due: Enter appropriate fees due.
  - a. Enter license fee according to payment codes in #30.

c. A \$10 late fee due, if renewal application is over 30 days late.

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b. Add \$200 PDMA fee if it applies to your firm. See PDMA requirements above\*.

d. Enter Total Payment Due by adding a, b and c.

32. Sign the application, print your name, print your title, and enter the date. All signatures must be original.

Make checks payable to: DEPARTMENT OF HEALTH SERVICES Mail Application and Check to: (below)

**Regular Mail:** California Department of Health Services

Food and Drug Branch - Cashier MS 7602

P.O. Box 997435

Sacramento, CA 95899-7435

Overnight Mail: California Department of Health Services Food and Drug Branch - Cashier 1500 Capitol Avenue, MS-7602 Sacramento, CA 95814

If further questions exist, please contact the FDB License Desk for Drug Manufacturing at (916) 650-6500, or visit our web site at: http://www.dhs.ca.gov/fdb/.